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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-18MY; Docket No. CDC-2018-0018]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on "Network Epidemiology of Syphilis Transmission (NEST)". The purpose of the NEST study is to address knowledge gaps in the transmission of syphilis among men who have sex with men (MSM) in the United States by exploring the role of sexual and social networks. Specifically, the goal of NEST is to pilot the use of survey instruments to collect complex longitudinal sexual network data among MSM at high risk for syphilis in the United States.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0018 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: Submit all Federal comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74,

Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Network Epidemiology of Syphilis Transmission (NEST) - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC's Division of STD Prevention (DSTDP) requests a three-year approval for a new data collection entitled, Network Epidemiology of Syphilis Transmission (NEST). CDC intends to collect study participants' sociodemographic, risk behavior, and insurance coverage information as part of study enrollment.

A cooperative agreement between CDC and three study grantees, two universities (Ohio State University and University of Illinois at Chicago) and one local health department (Baltimore City Health Department) in collaboration with a

university (Johns Hopkins School of Medicine), make this study possible. The recruitment of study participants as well as the data collection activities will be carried out at university-affiliated sites including local health departments, community lesbian, gay, bisexual, and transgender (LGBT) organizations, local STD clinics and HIV/AIDS care facilities.

The overall objective of NEST is to support the establishment of cohorts of MSM at high risk for syphilis, prospectively collect behavioral, social, and sexual network data, and biological specimens. Study participants will attend study visits every three months for a period of up to 24 months. NEST is a multi-site study, with a target enrollment of approximately 720 MSM aged 18 years and older from three geographic areas of the United States: (1) Chicago, Illinois, (2) Baltimore, Maryland, and (3) Columbus, Ohio.

At each study visit, researchers will interview participants and collect biological specimens (blood and urine) to facilitate testing for syphilis, gonorrhea, chlamydia, and HIV, which are part of the routine clinical care at participating sites. Researchers will collect data using Form 1—Questionnaire and Data Elements and directly submit the data electronically to the CDC NEST data manager. Researchers will not retain or collect individual patient personal identifying

information (e.g., name, address) on NEST data collection forms nor will they transmit personal identifying information to CDC.

The United States is currently experiencing an ongoing syphilis epidemic. MSM are disproportionately impacted by syphilis and the majority of incident syphilis cases in the United States occur among MSM. However, factors influencing syphilis transmission within this population, such as social and sexual network characteristics, sexual behaviors, and healthcare access and utilization, are poorly understood. In order to address these knowledge gaps, researchers must collect both individual-level and network-level data among this population. As such, we need to develop a better understanding of the feasibility of collecting complex sexual network data among this population. The collection of complex sexual network data and traditional individual-level data, such as demographics and individual-level sexual and social behaviors, will help to collectively address some of the knowledge gaps in the transmission dynamics and epidemiology of syphilis among MSM in the United States and point towards effective public health interventions to slow the spread of syphilis.

The goal of NEST is to pilot the use of survey instruments to collect complex longitudinal sexual network data among MSM at high risk for syphilis in the United States. The feasibility of data collection on basic information about recent partners of

persons diagnosed with syphilis is clear and is routinely performed by public health officials. However, the feasibility and optimal approaches for serial collection of complex sexual network data among populations that may have dynamic networks are not at all clear. Specifically, it is not clear what the optimal recruitment strategies are to recruit and enroll MSM at high risk for syphilis. Researchers have yet to define the optimal approaches for retaining men as study participants for follow-up visits over a defined study period. Furthermore, our proposed data collection activities survey format has not been established. For example, it is not known whether study participants would prefer a survey that is completely self-administered and whether data collected using a self-administered survey will result in complete and valid data being collected or whether a survey administered by study staff would be a better format.

CDC is not involved in data collection activities. The grantees will implement the testing and collect data and specimens from the participants.

Before starting any data collection activities, researchers will administer a short eligibility screener to prospective study participants. If deemed eligible, researchers will obtain participant consent. Upon consent, researchers will begin data collection, which will include a baseline visit and follow-up

visits every three months for a total follow-up period of 24 months. At each visit, participants will provide biological specimens (blood and urine) to facilitate testing for syphilis, gonorrhea, chlamydia, and HIV. In addition to providing biological specimens, participants will complete a standardized survey that researchers will deliver electronically on a tablet or computer and will collect information on the participants' sexual network, individual behaviors, healthcare access and demographics.

The survey consists of 13 questionnaire modules with a range of 5 to 15 questions per module. Researchers will deliver a small subset of sexual behavior questions to the participant closer to real time using an open survey format and a weekly format. The open survey format is a brief survey that participants can respond to at any to record a sexual encounter or other event. Researchers will send the weekly format on Sunday nights, with a reminder on Monday evening, to address sexual behavior in the last week. Researchers will deliver these brief surveys electronically to participants and each survey is expected to take two minutes or less. Study site investigators provided input (based on knowledge of relevant local communities) into development of the survey.

Researchers will store data collected on electronic devices on a secure web-accessible local server at each site, which will only be accessible with a user name and password.

The total estimated annualized hourly burden anticipated for this study is 6,828 hours.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Potential participants	Screener;	900	1	2/60	30
Site data manager	Form 1— Questionnaire	3	5	10	150
Study participant	Form 1— Questionnaire	720	5	1.5	5,400
Study participant	Smartphone survey	720	52	2/60	1,248
Total					6,828

Leroy A. Richardson,

Chief,

Information Collection Review Office,

Office of Scientific Integrity,

Office of the Associate Director for Science,

Office of the Director,

Centers for Disease Control and Prevention.

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